No. 18-127

IN THE
Supreme Court of the United States

AMGEN INC., AMGEN MANUFACTURING LIMITED, AND AMGEN USA, INC.,
Petitioners,

v.

SANOFI, AVENTISUB LLC, REGENERON PHARMACEUTICALS INC., AND SANOFI-AVENTIS U.S., LLC,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY FOR PETITIONERS

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REPLY FOR PETITIONER

The Federal Circuit refuses to follow §112(a)'s text and this Court's rulings, with severe consequences for life-saving biopharmaceutical innovation. Section 112(a) imposes a single written-description requirement covering two topics: Patents must "contain *a* written description *of* the invention, and *of* the manner and process of making and using it." 35 U.S.C. §112(a) (emphasis added). Section 112(a) provides a single standard for evaluating that written description's sufficiency: It must be "in such full, clear, concise, and exact terms as to enable any person skilled in the art * * * to make and use the same." *Ibid.*

But the Federal Circuit holds otherwise. Insofar as the written description is "of the manner and process of

making and using" the invention, the Federal Circuit applies the statutory "full, clear, concise" standard. It evaluates written description "of the invention," however, under a "possession" test of its own creation.

The Federal Circuit enshrined that "possession" standard en banc in *Ariad Pharmaceuticals, Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010). Sanofi-Regeneron defends that result but never reconciles it with § 112(a)'s text. The standard imposes burdens Congress never required. It defies this Court's precedents—precedents Sanofi-Regeneron ignores. The "possession" standard has "never been very enlightening." *Id.* at 1351. Experience has now proved it unmanageable, as it spawns ever-shifting sub-tests and evidentiary exceptions. This Court should restore the standard Congress wrote in § 112(a).

Sanofi-Regeneron's waiver arguments reduce to the notion that Amgen was required to ask the Federal Circuit for another en banc to overturn en banc precedent, or to ask the panel to disregard that precedent. This Court requires nothing of the sort. The Federal Circuit passed on the issue in this case: It held the "possession" standard applies, and it vacated the jury's written-description determination under that standard. Review is warranted.

I. THE QUESTION PRESENTED WARRANTS REVIEW

A. The Federal Circuit's "Possession" Standard Defies Statutory Text

The Federal Circuit reads § 112 to impose two different standards for "written description" depending on whether the description addresses "the invention" or "the manner and process of making and using it." That defies § 112's text.

1. Sanofi-Regeneron ignores §112's grammatical structure. See Pet. 19-23. Section 112 imposes a single requirement of "*a* written description." Three prepositional phrases follow, *each* modifying "written description." The written description must be "*of* the invention." It must be "*of* the manner and process of making and using" the invention. And the written description must be "*in* such full, clear, concise, and exact terms as to enable" skilled artisans to practice the invention. As Amgen's chart (Pet. 19) demonstrates—and Sanofi-Regeneron ignores—§112 thus requires the *written description* (whether "of the invention" or "of the manner and process of making and using it") to meet the "full, clear, concise * * * as to enable" standard.

Sanofi-Regeneron posits that, if Congress intended to subject description "of the invention" to an "enablement standard," it would have reduced the "textual separation" between the two things that must be described by omitting the comma, and the second "of," from the phrase "'of the invention, *and of* the [manner and process] of making and using.'" Opp. 28. Not so: As Amgen explained (Pet. 21 n.5), the comma after "of the manner and process of making and using it," separates it from the phrase "in such full, clear, concise, and exact terms as to enable," showing that Congress intended the latter standard "to apply to all the antecedents instead of only to the immediately preceding one." 2A N. Singer, *Sutherland Statutory Construction* §47:33 (7th ed. 2017). Sanofi-Regeneron's "textual separation" hypothesis is neither a grammatical rule nor a canon of construction.

Sanofi-Regeneron urges that *Ariad*'s "interpretation avoids surplusage," ensuring inventors provide "a written description of the invention * * * *as well as* a written description explaining how to make and use" it. Opp. 27.

But so does Amgen's. Pet. 17, 19-20. Amgen agrees that merely describing how to make and use is insufficient. To provide a written description "of the invention," one must say what the invention *is*. And requiring a "written description," both of the invention and how to make and use it, to be "in such full, clear, concise, and exact terms as to enable" makes sense. Describing the invention, so artisans know *what* to make, is part-and-parcel of enabling artisans to make and use it. See *Schriber-Schroth Co.* v. *Cleveland Tr. Co.*, 305 U.S. 47, 57 (1938) (inventor must "describe his invention so that others may construct and use it").

Sanofi-Regeneron urges (Opp. 27-28) that the "parallel" between §112(a)'s requirement that inventors describe "'the manner and process of *making* and *using*'" the invention, and the standard requiring the description to be sufficiently full, clear, and exact to enable skilled artisans "'to *make* and *use*'" it, confines the statutory standard to that portion of the written description. Supposed "parallelism" does not change basic grammar.[1] Section 112 provides a single statutory standard to govern written description, regardless of topic.

2. Sanofi-Regeneron identifies *nothing* in §112(a)'s text to support imposing a "possession" standard for "written description of the invention." It is not "inherent" in the word "'invention.'" Opp. 29. Requiring patentees to *describe* the invention so artisans understand *what* it is—enabling them to make it—is not the same as requiring patentees "to show" that the inventor posses-

[1] Indeed, such "parallelism" is "disfavored," as "the law does not use redundant language." *Ariad*, 598 F.3d at 1362-1363 (Rader, J., dissenting).

sed it—whatever that means. *Ibid.* Even that is not "precisely the standard the Federal Circuit applies." *Ibid.* The panel here held that "[d]emonstrating possession 'requires' * * * a patentee [to] disclose 'a representative number of species falling within the scope of the genus or structural features common to the members of the genus.'" Pet. App. 8a. That "possession" standard, with its specialized sub-tests, is anything but "inherent" in the statute.

This Court has "cautioned" the Federal Circuit "that courts should not read into the patent laws limitations and conditions which the legislature has not expressed." *Bilski* v. *Kappos*, 561 U.S. 593, 602 (2010). The Federal Circuit's construction of § 112(a) does exactly that, imposing a "proof of possession" standard nowhere in the statute. See Pet. 23-24.

B. The Federal Circuit's "Possession" Standard Defies History and Precedent

Sanofi-Regeneron urges that, "[s]ince the first Patent Acts, Congress has consistently distinguished between * * * description of the invention and the required enablement of how to make and use" it. Opp. 29-30. But the first Patent Acts required written description of *the invention* to be sufficiently full, clear, concise, and exact *to enable* others to make it. The 1790 Act required "a description * * * of the thing * * * invented" that was "so particular" as to *both* "distinguish the invention * * * from other things before known and used" *and* "to enable" skilled artisans "to make, construct, or use the [invention]." Pet. App. 72a. The 1793 Act did likewise. See

Pet. App. 73a (similar). Neither included a "possession" standard.[2]

1. Sanofi-Regeneron dates the "possession" standard not to 1790, but to "at least 1967." Opp. 30. "Congress," it claims, "was hardly required to explicitly codify a doctrine" courts "were already correctly applying." *Ibid.* But the current § 112—from the 1952 Patent Act—predates the "possession" standard. See Pet. 26. Congress did not "codify" it in § 112(a). The Federal Circuit invented the "possession" standard later.

Congress's failure "to disturb" the "possession" test when amending other sections of the Patent Act, Opp. 30, 33-34, "does not imply" Congress's "acceptance" of the Federal Circuit's view, *Helvering* v. *Hallock*, 309 U.S. 106, 120 n.7 (1940). Sanofi-Regeneron identifies no instance where Congress even *considered* the possession standard. See *Kimble* v. *Marvel Entm't, LLC*, 135 S. Ct. 2401, 2409-2410 (2015). "The verdict of quiescent years"—explained by Congress's "unawareness, preoccupation, or paralysis"—"cannot * * * baptize a statutory gloss that is otherwise impermissible." *Zuber* v. *Allen*, 396 U.S. 168, 185-186 n.21 (1969).

2. This Court has made clear that written description—"of the invention"—is governed by the "full, clear, concise, and exact terms as to enable" standard. *Markman* v. *Westview Instruments, Inc.*, explained that patents must "contain[ ] a specification *describing the invention* 'in such full, clear, concise, and exact terms as *to*

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[2] Tellingly, current § 112(a) omits those Acts' requirement that patentees "distinguish the [invention] from all other things before known." The claims required by § 112(b), and other provisions, serve that role. Pet. 7-8.

enable'" skilled artisans "'to make and use the same,'" tracing that standard to the 18th century. 517 U.S. 370, 373, 379 (1996) (emphasis added); Pet. 24-25. This Court said the same in *Universal Oil Products Co.* v. *Globe Oil & Refining Co.*, 322 U.S. 471, 484 (1944), and *The Telephone Cases*, 126 U.S. 1, 536 (1888). See Pet. 25-26. The Federal Circuit's holding that the "phrase 'in such full, clear, concise, and exact terms as to enable' * * * modifies *only* 'the written description . . . of the manner and process of making and using'" the invention—*not* written description of the invention—contradicts this Court's decisions. *Ariad*, 598 F.3d at 1344 (emphasis added). Sanofi-Regeneron ignores those decisions.

Sanofi-Regeneron invokes *Schriber-Schroth*, describing that case as holding that, "[r]egardless of what the patent enabled, the patent 'does not extend *beyond the invention described and explained* as the statute requires.'" Opp. 32 (emphasis added) (quoting *Schriber-Schroth*, 305 U.S. at 57). Amgen never suggested otherwise. Under §112(a), the written description must be (1) "of the invention," *and* (2) it must be "in such full" terms as "to enable." The first requirement is not met if the inventor fails to describe *the invention*. *Schriber-Schroth* stands only for the proposition that description of the invention is inadequate where it describes one thing—there, pistons with "extremely rigid" webs—but the inventor later attempts to claim something entirely different—"webs [that] were laterally flexible rather than rigid." 305 U.S. at 58-59. That hardly supports an extra-statutory "possession" standard. *Schriber-Schroth*, moreover, explains that the statute's "object * * * is to require the patentee to describe *his invention* so that others *may construct and use* it." *Id.* at 57 (emphasis added). It endorses the very construction the Federal Cir-

cuit rejects. And far from supporting Sanofi-Regeneron (Opp. 32), *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62 (1854), states that, "the *invention* shall be *so described*, *that*" skilled artisans "*shall be able to construct the improvement* from the description given," *id.* at 120 (emphasis added)—not that it must show "possession."

3. Sanofi-Regeneron's invocation of the "possession" test's supposedly "settled nature," Opp. 32, hardly weighs against review. The "possession" standard is entrenched, but unstable: The Federal Circuit's *application* gyrates through adoption and elimination of inflexible sub-tests, as this case illustrates. See Pet. 27-32; *Anascape, Ltd.* v. *Nintendo of Am., Inc.*, 601 F.3d 1333, 1342 (Fed. Cir. 2010) (Gajarsa, J., concurring). Sanofi-Regeneron identifies no reliance interests that would be upset were § 112 correctly construed. The current standard impedes innovation. See Pet. 27-29. The longevity of an error has never been a barrier to review where the Federal Circuit adopts "a narrow, rigid [approach] inconsistent with" statutory text and this Court's "precedents." *KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 427-428 (2007).

C. The Issue Is Exceptionally Important

Nor does the petition "[o]verstate[ ] * * * [i]mportance." Opp. 34. The issue was important enough for the Federal Circuit to consider it en banc and to prompt dozens of *amicus* briefs there. Opp. 26. It is important enough for four of the Nation's leading biopharmaceutical innovators to press for review as *amici* here. Those companies "spend billions of dollars researching and developing cutting-edge therapies" for life-threatening illnesses like atrial fibrillation (Bristol-Myers Squibb), autoimmune diseases (Morphosys), Parkinson's (UCB Biopharma), and cancer (Bavarian Nordic). Amicus Br. 1; see *id.* at 3. They agree that "[t]he Federal Circuit's ap-

proach" impedes biopharmaceutical innovation, making it "exceedingly difficult to obtain robust patent protection * * * in this field." *Id.* at 1.

The issue's importance has not waned since *Ariad*. Opp. 34. The written-description requirement remains a "doctrinal wildcard," creating "uncertainty" in biotechnology. C. Holman, *Developments in Synthetic Biology Are Altering the IP Imperatives of Biotechnology*, 17 Vand. J. Ent. & Tech. L. 385, 412-413 (2015). *Ariad*'s statutory interpretation is still criticized as "breathtakingly bad." N. Goldfarb, *Judicial Howlers:* Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., LAWnLinguistics (July 26, 2012), https://lawnlinguistics.com/2012/07/26/judicial-howlers-ariad-pharmaceuticals-inc-v-eli-lilly-co/; see also A. Sawicki, *The Central Claiming Renaissance*, 103 Cornell L. Rev. 645, 719 (2018).

Nor does Amgen's *amicus* brief in *Ariad* disprove importance. Opp. 3, 15, 24, 29, 34-35. Amgen expressed concern that "requiring excessive detail or analysis in a patent disclosure" would "stifle innovation." Amgen Amicus Br. 23, *Ariad*, 598 F.3d 1336 (No. 2008-1248), 2009 WL 4616154. But the "pendulum ha[d] not swung that far." *Ibid.*

It has now. Unmoored from § 112's text, the "possession" standard has spawned ever-changing sub-tests with a disparate impact on biotechnology. See Pet. 28-33. This case proves the point: The Federal Circuit abandoned its own "newly characterized antigen" sub-test for possession as "dicta" despite 15 years of application. See Pet. 29-30. And it overturned precedent requiring the exclusion of post-priority-date embodiments, creating an exception for purposes of that court's "representative species" sub-test. See Pet. 30-31. That instability confirms the consequences of departing from statutory text.

II. THIS CASE IS AN APPROPRIATE VEHICLE

A. The Decision Below Passes on the Question Presented

Sanofi-Regeneron admonishes that this is a "court of review, not of first view." Opp. 2, 13, 18-19. But Sanofi-Regeneron admits this Court would not be the "first" to "view" the issue: It insists that the Federal Circuit's "'possession' standard" is "settled patent law," reaffirmed by the Federal Circuit en banc in *Ariad*. Opp. 2; see Opp. 24, 26. And while this Court does not review questions "neither pressed nor passed on below," Opp. 20, the issue was "passed on": Sanofi-Regeneron concedes that the panel "recited and applied the Federal Circuit's existing written description law." *Ibid.*; see Pet. App. 7a-9a, 11a, 17a. Indeed, reaffirming that standard, it overturned not just the jury's written-description verdict, but also the Federal Circuit's own "newly characterized antigen" sub-test and evidentiary standards. Pet. App. 12a, 19a; see Pet. 29-31. That supports review. See *United States* v. *Williams*, 504 U.S. 36, 41 (1992).

Sanofi-Regeneron's arguments about "preserv[ing] the issue before the district court and Federal Circuit panel," Opp. 16, are frivolous. Asking the district court or the panel to depart from *Ariad* "would have been an exercise in futility." Opp. 19. Those courts were bound by that precedent (and Amgen had prevailed in district court). See *Tex. Am. Oil Corp.* v. *U.S. Dep't of Energy*, 44 F.3d 1557, 1561 (Fed. Cir. 1995) (en banc). There is no waiver where "the argument would [have] be[en] futile" because the panel "had no authority to overrule" binding precedent. *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 125 (2007).

Sanofi-Regeneron further argues that, despite the Federal Circuit having already resolved the issue en

banc, Amgen was required to seek *re*-en banc. This Court does not require that. It has granted review despite the identical argument. Compare *Halo Elecs., Inc.* v. *Pulse Elecs., Inc.*, 136 S. Ct. 1923 (2016) (overturning *In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (en banc)), with Opp. 5-7, *Stryker Corp.* v. *Zimmer, Inc.* (No. 14-1520) (urging that petitioner failed to seek to overturn *Seagate* below). Sanofi-Regeneron cites (Opp. 15-16, 18-19) garden-variety cases where this Court declines to review a novel argument on unsettled issues, where the litigant never raised it and the court of appeals never addressed it. See, *e.g.*, *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 56 n.4 (2002) (refusing to review argument involving open question of maritime law). None of those cases suggests that litigants must ask lower courts to overrule en banc precedent to obtain review of a legal standard articulated, reaffirmed, and applied to them below.

Here, moreover, the Federal Circuit invoked the "possession" standard to *eliminate* the longstanding "newly characterized antigen" test Amgen had invoked, deeming it contrary to *Ariad*'s "possession" standard. See Pet. 29-30; Pet. App. 12a-19a. And it remanded for consideration of *different* (non-statutory) sub-tests for the possession requirement. Pet. 30-31. The accusation that "Amgen cited with *approval* the written description law it now challenges," Opp. 2; see Opp. 7-13, 17, thus rings hollow. Amgen appropriately cited *Ariad* because it was *binding law*. The notion that the panel did not "pass upon" the issue, having rejected Amgen's position as contrary to the "possession" standard, defies credulity.

B. Review Is Warranted Now

The Federal Circuit's remand does not weigh against review. Opp. 22-23. If this Court grants the petition,

Amgen would agree to stay the trial so it can be conducted under the correct standard. Sanofi-Regeneron does not say it would oppose. Nor is there any "risk of mootness," Opp. 23, regardless.[3]

The viability of the Federal Circuit's "possession" standard is a "'clear-cut issue of law that is fundamental to the further conduct of the case.'" Pet. 34; see *United States* v. *Gen. Motors Corp.*, 323 U.S. 373, 377 (1945) (reviewing issue despite remand where issue was "fundamental to the further conduct of the case"). Sanofi-Regeneron speculates the case might be resolved identically regardless. Opp. 13-14, 21. But the differences for appellate review, and retrial if warranted, are night and day. If the statutory standard prevails, the lower courts could no longer apply "a narrow, rigid [approach] inconsistent with" statutory text and this Court's "precedents." *KSR*, 550 U.S. at 427-428. The Federal Circuit could not straightjacket the evidence and the jury's consideration of it to whether Amgen's patent satisfies the "representative-species" or "structure-function" subtests to prove "possession"—as the decision below requires. See Pet. App. 7a-19a. Nor would any retrial require an examination of after-developed embodiments and their relationship to "possession." See Pet. 30-32.[4] The question would be the one *§ 112(a)* identifies:

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[3] If Amgen prevails on written description at trial on remand, Sanofi-Regeneron will undoubtedly appeal, which would raise the propriety of the possession standard. If Sanofi-Regeneron prevails at trial, Amgen will challenge the possession standard on appeal.

[4] Indeed, if the standard for the description "of the invention" is refocused on the statutory text, and not the "possession" sub-tests, the Federal Circuit may reconsider whether a remand on enablement is necessary: It ordered a new trial on enablement "[f]or many of the same reasons" in its written-description ruling. Pet. App. 12a.

Whether Amgen described its "invention," and did so with sufficient clarity and precision to enable skilled artisans to make and use it.

CONCLUSION

The petition should be granted.

Respectfully submitted.

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